K072045



## 5. 510(k) Summary

OCT 2 2 2007

vidacare®

722 Isom Road
San Antonio, TX 78216
210-375-8500

SUMMARY

| | |
|---|---|
| Submitter's name: | Vidacare Corporation |
| Address: | 722 Isom Road<br>San Antonio, TX 78216 |
| Phone: | 210-375-8500 |
| Fax number: | 210-375-8537 |
| Name of contact person: | Grace Holland<br>Regulatory Specialists, Inc<br>3722 Ave. Sausalito<br>Irvine, CA 92606<br>Phone: 949-262-0411<br>Fax: 949-552-2821 |

Date the summary was prepared: July 23, 2007

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|---|---|
| Name of the device: | OnControl™ Bone Marrow Biopsy System |
| Trade or proprietary name: | Bone Biopsy/Aspiration System |
| Common or usual name: | Bone Biopsy Needle |
| Classification name: | Biopsy instrument |

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

| | *510(k) Number* | | *Trade or Proprietary or Model Name* | | *Manufacturer* |
|---|---|---|---|---|---|
| 1 | K062833 | 1 | EZ-IO® Bone Marrow Aspiration System | 1 | Vidacare Corp. |
| 2 | K043523 | 2 | InterV TrapLok ™ Bone Marrow Biopsy Needle | 2 | Medical Devices Technologies |
| 3 | K953064 | 3 | Bone Marrow Harvest System | 3 | BioAccess |

Description of the device:

The OnControl™ Bone Marrow Biopsy System consists of a reusable battery powered driver (similar to the one cleared for bone marrow aspiration in adults via K062833) connected to a disposable bone marrow biopsy needle set. The 11 gauge, 152mm cannula is identical in gauge and length to the predicate InterV® TrapLok, cleared via K043523. The BioAccess Bone Marrow Harvest System is an FDA-cleared powered biopsy device (K953064), which has a battery power source similar to Vidacare's product.

Upon activation, the driver assists the clinician to insert a biopsy needle set through the cortex of the bone. The driver is then separated from the hub of the biopsy needle set by retracting the collar on the driver coupler. The trocar/stylet is then removed from the needle set leaving an 11-gauge biopsy cannula firmly seated in the bone. A standard Luer lock (part of the 11 gauge cannula) then permits attachment of a standard syringe for aspiration of bone marrow. The driver/coupler is then reattached to the biopsy cannula and the power driver is activated. The biopsy cannula is advanced to the desired depth in the medullary cavity for capturing adequate bone marrow biopsy samples. The entire needle assembly is then withdrawn from the patient using power to facilitate removal. At this point the driver is separated from the biopsy needle assembly; the specimen is removed from the biopsy cannula by attaching an alignment guide to the cutting end of the biopsy cannula and pushing out the bone specimen with an ejector rod. The cannula length is 152mm (6"), which is identical to the predicate InterV® TrapLok, K043523.

Indications:

The OnControl™ Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy.

Summary of the technological characteristics of our device compared to the predicate device:

The predicates and the OnControl™ Bone Marrow Biopsy System were compared in the following areas and found to have similar technological characteristics and to be equivalent.

Indications for Use
Target Population
Driver Design Features

Needle Design
Technique
**Sterility**
**Biocompatibility**
Anatomical Sites
Where Used

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vidacare Corporation
% Regulatory Specialist, Inc.
Ms. Grace Holland
Regulatory Specialist
3722 Sausalito
Irvine, California 92606

OCT 2 2 2007

Re: K072045
Trade/Device Name: OnControl™ Bone Marrow Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW, FCG
Dated: September 13, 2007
Received: September 17, 2007

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 4. Indications for Use Statement

### Indications for Use

510(k) Number (if known): _____

Device Name: OnControl™ Bone Marrow Biopsy System

Indications for Use:

The OnControl™ Bone Marrow Biopsy System is intended for bone marrow aspiration and biopsy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072045